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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE JUL 13 2007

APPLICANT: AUSTIN, et al.

SERIAL NO.: 10/607,010 Group Art Unit: 3733

FILED: June 26, 2003 EXAMINER: Shaffer, Richard R.

FOR: EXTERNAL FIXATION APPARATUS AND METHOD

ATTORNEY DOCKET NO.: 39262/285776  
(01-31-0780)

DATE: July 13, 2007

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**PRE-APPEAL BRIEF REQUEST FOR REVIEW**

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Sir:

Responsive to the Office Action mailed December 19, 2006 and the Final Office Action mailed June 22, 2007, Assignee requests a pre-appeal brief review in the above-identified application. A concise statement setting forth the reasons for the request is set forth below.

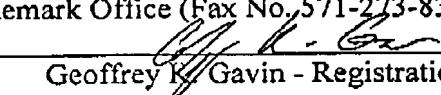
**REASONS FOR THE REQUEST**

The Examiner's rejections in the Final Office Action, as well as the earlier rejections in the prior office actions, omit essential elements required to establish a *prima facie* rejection. Specifically, the Examiner has not provided a reference that teaches or suggests at least the claim limitation of a "pivot arm comprising a first end portion and a second end portion, wherein the first end portion and the second end portion are configured to translate transversely relative to one another and to a longitudinal axis of the pivot arm," as recited in

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I hereby certify that this correspondence is being facsimile transmitted to the U.S. Patent and Trademark Office (Fax No. 571-273-8300) on July 13, 2007.

  
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independent claims 1 and 18, or "adjusting the first and second end portions of the pivot arm relative to each other and transversely relative to a longitudinal axis of the pivot arm to precisely reduce the fracture," as recited in independent claim 30. Additionally, the Examiner has not provided a reference that teaches or suggests at least the claim limitation of a pin clamp snap fit onto a shaft of a pivot arm (or second member), wherein the pin clamp comprises a push or pull mechanism or a locator pin "that is received within the groove of the shaft when the pivot arm and pin clamp are coupled and removed from the groove to disengage the pin clamp from the pivot arm," as recited in independent claims 18 and 25. Finally, the Examiner has failed to show proper motivation for making his proposed modifications in setting forth the various rejections under 35 U.S.C. § 103(a). In light of these clear factual deficiencies in the rejections, a pre-appeal panel review is requested.

**REMARKS**

Claims 1-5, 17-21, 23-25, 28-34, 36, and 41-43 are now pending. Of those, claims 1, 18, 25, and 30 are independent claims. In the Final Office Action, the Examiner rejected claims 1 and 30 under 35 U.S.C. § 103(a) as being unpatentable over PCT Publication No. WO 00/40163 to *Faccioli et al.* ("Faccioli") in view of U.S. Patent No. 5,405,347 to *Lee et al.* ("Lee"). The Examiner rejected claim 25 under 35 U.S.C. § 103(a) as being unpatentable over U.S. Patent No. 5,827,282 to *Pennig* ("Pennig"). The Examiner rejected claim 18 under 35 U.S.C. § 103(a) as being unpatentable over *Pennig* in view of *Lee*.

**Independent Claims 1 and 30**

Claim 1 recites, *inter alia*, a pivot arm comprising a first end portion and a second end portion, wherein the first end portion and the second end portion are configured to translate transversely relative to one another and to a longitudinal axis of the pivot arm. (See 4/12/07 Response, pp. 2, 13-14.) In the December 19, 2006 Action, the Examiner rejected claim 1 as anticipated by *Faccioli*. (See 12/19/06 Action, p. 3.) Following a telephone interview on March 22, 2007 and a minor modification to claim 1, the Examiner now rejects claim 1 as obvious in view of *Faccioli* combined with *Lee*. (See 6/22/07 Action, p. 2.)

Assignee clearly explained why claim 1 is not anticipated by *Faccioli*. (See 4/12/07 Response, pp. 14-15.) It appears the Examiner accepted this reasoning in view of the new §

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103 rejection; however, this is somewhat unclear given the Examiner's assertion that *Faccioli* discloses all of the elements of claims 1-5, 17, 30-34, 36, and 41 "except for carriage having two threaded holes . . ." because the claim limitation identified by the Examiner in the rejection is present only in claim 4, not in claim 1. (See 6/22/07 Action, pp. 2-3.) Nevertheless, as explained on pages 15-16 of the 4/12/07 Response, *Lee* does not teach or suggest a pivot arm with first and second end portions that are configured to translate transversely relative to one another and to a longitudinal axis of the pivot arm, either alone or in combination with *Faccioli*.

The adjustable connector 10 of *Lee*, which includes lateral adjustment mechanism 12 and angular adjustment mechanism 70, has openings used to receive two separate external fixator rods and to improve movement of the two fixator rods with respect to one another for maximum flexibility. (See 4/12/07 Response, pp. 15-16.) *Lee* does not teach any mechanism by which end portions of a structure, such as the recited pivot arm, are configured to translate transversely with respect to one another and its longitudinal axis. Following the Examiner's reasoning, one would apparently saw the stem 20 of *Faccioli* in half and insert the adjustable connector 10 of *Lee* in between the two halves (along with needing to make innumerable other modifications) to obtain the subject matter of claim 1. This does not make sense and indeed there is no teaching, suggestion, or motivation in either *Faccioli* or *Lee* or elsewhere in the prior art to do so.

Figs. 8 and 9 of *Lee* show the significant amount of lateral and angular adjustment between the two external fixator rods that the adjustable connector 10 of *Lee* provides, and the Examiner acknowledges that *Lee* was built for adjustment of the separate fixator rods in an infinite amount of axes. (See 6/22/07 Action, p. 3.) If one skilled in the art was looking to address the issue of fine adjustment during fracture reduction (see Background section of the application), one skilled in the art would not be motivated to look to *Lee* to address this concern. For at least the above reasons, the Examiner failed to establish a *prima facie* basis for unpatentability of claim 1. Moreover, the Examiner has never separately addressed independent method claim 30, merely grouping it with claim 1 in the prior rejections. Thus, the Examiner likewise failed to establish a *prima facie* basis for unpatentability of claim 30.

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Claims 18 and 25 recite, *inter alia*, a pin clamp that releasably snap fits onto a shaft of a pivot arm (or second member), wherein the pin clamp comprises a push or pull mechanism or a locator pin "that is received within the groove of the shaft when the pivot arm and pin clamp are coupled and removed from the groove to disengage the pin clamp from the pivot arm." In response to claim amendments made in the 4/12/07 Response and discussions during the March 22, 2007 telephone interview, the Examiner stated new rejections in the Final Office Action – rejecting claim 25 as obvious in view of *Pennig* alone and claim 18 as obvious in view of *Pennig* combined with *Lee*. However, contrary to the Examiner's assertions, *Pennig* does not teach a pin clamp that snap fits onto a shaft, nor does *Pennig* teach the recited push or pull mechanism or locator pin also recited in claims 18 and 25.

First, the Examiner admits that *Pennig* does not teach a snap-fit connection between the pin clamp and the pivot arm (the pin does not snap fit into the groove, in the Examiner's words) (see 6/22/07 Action, p. 4), but the Examiner asserts it would have been obvious to modify *Pennig* so that the pin clamp and pivot arm snap fit together to provide a surgeon with an audible and tactile response to confirm a stable connection between the two components has been made. However, the Examiner is ignoring that the alleged pin clamp of *Pennig* (item 3 in Figs. 1 and 2) and shaft of the pivot arm (item 6) do not releasably snap fit to one another, but are permanently secured to each other. There is no teaching that the half shell 3 and shank portion 6 of *Pennig* are separable from one another (absent complete destruction of the device), and, because the two components are permanently secured prior to use by the surgeon, there is no motivation to modify *Pennig* in any manner to provide a snap fit connection as the Examiner suggests would benefit a surgeon during use.

Second, the pin 16 inserted into groove 15 in *Pennig* is permanently located within half shell 3 to ensure axial retention of stem 6 within the half shell 3. Half shell 3 rotates about axis 8, but there is no teaching that pin 16 is removable at any time from groove 15 to disengage half shell 3 from stem 6 or for any other purpose. The Examiner's reliance on an internal, permanently secured pin, such as pin 16 of *Pennig*, suffers from the same flaws as the Examiner's prior citation to pin 35 of *Faccioli* in earlier rejections of claims 18 and 25,

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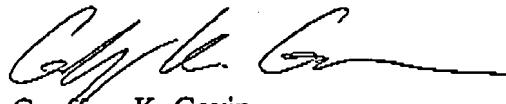
which have since been overcome. (See 4/12/07 Response, pp. 17-18.) Furthermore, as can be seen from the drawings in *Pennig*, pin 16 clearly does not teach or suggest a push or pull mechanism as explicitly recited in claim 25.

For at least the above reasons, the Examiner failed to establish a *prima facie* basis for unpatentability of claims 18 and 25. With respect to claim 18, the Examiner also failed to establish a *prima facie* basis for unpatentability for the reasons similar to those described above with respect to claim 1 and the *Lee* reference. Furthermore, the Examiner identified rotary joint 11 of *Pennig* as allegedly teaching the pivot arm recited in claim 18, but it is unclear how the entire joint of *Pennig* represents the pivot arm as the Examiner has not identified the recited first and second end portions of the pivot arm, or how the shank portion 6 of *Pennig* extends transversely from the second end portion of the pivot arm as recited in claim 18. As such, the Examiner's rejection of claim 18 in view of *Pennig* combined with *Lee* cannot be fully understood and omits essential elements needed for a *prima facie* rejection.

**CONCLUSION**

For the reasons set forth above, Assignee respectfully requests that the application be allowed on the existing claims.

Respectfully submitted,



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Date: July 13, 2007

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